



Public Health
England

Protecting and improving the nation's health

Patient re-engagement exercise for those who have been diagnosed with hepatitis C – Information for Operational Delivery Networks (ODNs)

About Public Health England

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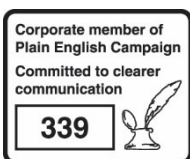


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Information for Operational Delivery Networks about the NHS England (NHSE) and Public Health England (PHE) patient re-engagement exercise for people who have been previously diagnosed with hepatitis C

Untreated hepatitis C infection causes cirrhosis and liver cancer. Very effective, well tolerated oral therapies are now available on the NHS. PHE and NHSE are keen to ensure that all patients with hepatitis C are offered these curative therapies.

To enable people previously diagnosed with hepatitis C to be treated for their infection, NHSE and PHE have organised a national 'patient re-engagement exercise' to help find and treat people with hepatitis C virus (HCV) infection. This document provides further information about this important initiative.

General information on the re-engagement exercise

1. What is the purpose of this re-engagement exercise?

Public Health England (PHE) and NHS England (NHSE) estimate that there are tens of thousands of people currently living with diagnosed hepatitis C infection who are not in contact with treatment services. Many of these people may have been diagnosed when little about the natural history of HCV-related disease was less certain and/or when treatment options were limited with sub-optimal outcomes.

Now that new direct acting antiviral drugs (DAAs) are available that can lead to a rapid cure in the vast majority of patients, it is important that every effort is made to re-engage people with treatment services so they can consider the treatment options available to them. As many of those infected with HCV come from vulnerable populations (migrants, people who inject drugs) who experience poorer access to treatment and outcomes, an active approach is likely to be of particular benefit.

NHS England, with its ambition to deliver treatment and care to infected eligible patients, Public Health England with its duty to monitor and control communicable diseases, and The Hepatitis C Trust, with its advocacy role as the national charity for people with hepatitis C, are all committed to re-engage previously diagnosed people with treatment services. This is part of wider concerted efforts to eliminate hepatitis C as a major public health threat in England before 2030.

With this in mind, PHE has obtained Caldicott permission to share with the lead hospital clinician of operational delivery networks (ODN), a list of people resident in their ODN area who have been diagnosed with HCV in NHS laboratories between 1996 and 2017 (inclusive) and reported to PHE for surveillance purposes. As laboratory reports contain patient identifiable information, where sufficient identifiers exist, PHE can match these patients to the NHS Spine patient demographic service (PDS), and to other national surveillance datasets (deaths, transplants, HCV treatment) to generate a list of patients who are known to be alive, registered with a GP and not known to be already under specialist care or completed treatment with the new DAAs.

The aim of this exercise is to improve case-finding and engagement of patients to establish whether they are currently infected and would benefit from curative HCV treatment.

2. Why is this exercise being done now?

NHS England has invested significant sums recently to roll-out the new highly effective oral drugs (Direct Acting Antivirals (DAAs)) to patients through ODNs. NHSE are undertaking strategic drug procurement with the ambition to achieve elimination goal of hepatitis C well before 2030. To scale up treatment to the levels required for elimination of hepatitis C as a public health threat, case-finding needs simultaneously to ramp up to identify and refer undiagnosed and previously diagnosed patients who have not engaged in specialist care.

3. When will the exercise be launched?

PHE released patient lists to the ODNs in September 2018, after a signed Memorandum of Understanding (MoU) was returned to PHE from the ODN. It is expected the ODNs will start informing GPs and contacting patients over the subsequent months.

In parallel PHE, NHSE and the Hepatitis C Trust together with RCGP will launch communications to raise awareness of this exercise among key stakeholders and patient groups. ODNs and local PHE teams should also engage with local stakeholders to raise awareness.

4. How is this exercise being implemented?

Following Caldicott approval, PHE's national hepatitis surveillance team has generated a list of patients diagnosed between 1996 and 2017 and reported to PHE who have been successfully matched to a current GP, are known to be alive and not known to be already under specialist care or completed treatment with the new DAAs.

The patient lists will be shared ODNs under a MoU outlining conditions of use of the data for direct patient care only. While the ODNs should decide locally how best to implement the case-finding in their patch, there are expectations (outlined in the MoU) that the ODN should:

- mitigate information governance risks as required for Caldicott approval to release data;
- minimise workload on GPs by leading on contacting patients, doing confirmatory testing and managing contacts, and providing support where a GP practice has many diagnosed patients;
- ensure arrangements are in place for the ODN to contact patients, following up non-responders, providing confirmatory HCV testing, offering counselling and advice on HCV test results, including negative results counselling, and HCV testing of household and sexual contacts.
- ensure diagnosed patients have access to appropriate care pathways, including for other co-morbidities, supportive care, complementary therapies, substance misuse services (as appropriate), hepatitis A and B vaccination and harm minimisation advice.

5. What are the information governance (IG) risks of sharing these patient confidential data?

The main information governance risks are related to the fact that the PHE held laboratory data were submitted to PHE or its predecessor organisations, for public health surveillance purposes not for direct patient care, and hence completeness of identifiers is variable. The main risks that were identified by the Caldicott panel for mitigation are:

- a) accidental disclosure as patient letter is sent out to an old address (if the NHS spine patient demographic service (PDS) not up to date or name is incorrect on the PDS or lab systems)
- b) incidental or inappropriate notification whereby a) the letter is the first a person is informed of their diagnosis; b) the patient has been treated / cleared infection spontaneously and is no longer HepC positive; c) patient had actively chosen to not have contact with health services; d) the patient did not want their diagnosis shared with GP /other health services.

- c) false positives – whereby a person without HepC is told they have it through the letter (because of erroneous coding at testing laboratory / not removed following negative confirmatory test / poorer performance of older assays).
- d) missed patients whereby because of incomplete or incorrect information entered on NHS laboratory or PDS systems, a diagnosed patient could not be linked to a GP and identified for contacting as part of this exercise.

6. What are the ODNs expected to do to mitigate IG risks?

ODNs will need to do further quality checks of the data with their local IT systems (e.g. laboratory, patient administrative, and treatment databases) to verify the status of the patients as far as possible.

ODNs are expected to write to individual patient's GPs to let them know that they will be contacting their patients to offer confirmatory testing (HCV RNA) and assessment for HCV treatment. This will give GPs an opportunity to raise any concerns they may have about the patient being contacted directly. After 4 weeks from contacting the GP, in the absence of any concerns from primary care, the ODN lead may contact the patient directly.

Reasons returned by primary care for not contacting the patient may include:

- not clinically appropriate (e.g. due to other conditions such as terminal diagnosis or recent patient decision to decline referral)
- patient is not contactable (e.g. due to movement out of area or is deceased)
- patient or laboratory diagnosis details are incorrect
- patient has had a recent negative hepatitis C PCR test
- patient is currently on hepatitis C treatment or attending a hepatology/infectious diseases outpatient clinic for monitoring of hepatitis C.

7. Who will be contacting the patients and testing them for HCV RNA?

If no concerns have been raised by their GP, to minimise burden on GP services, the default position (unless other arrangements have been agreed locally with GPs) is that the ODN clinical lead will contact the patient and offer confirmatory testing (HCV RNA), and assessment for treatment if HCV infected. The ODNs are advised to follow-up patients who do not respond initially with multiple attempts of contact as is practically possible.

8. Are template letters for contacting GPs and patients available?

Yes – PHE and NHSE with input from RCGP, GPC and the Hepatitis C Trust have developed template letters for:

- ODN writing to a GP about a patient on the PHE list that the ODN wishes to contact for treatment assessment
- ODN writing directly to patient to invite for confirmatory testing

It is acknowledged these letters may be adapted for local use, but please avoid substantial changes as the ODN to GP letter text has been carefully worded to minimise the “ask” of GPs and has been agreed by RCGP and the GPC. GPC were clear that GPs should not be presented with a list of patients and asked to check all their details are correct.

A FAQ for GPs and patients have also been drafted which can be included with letters to GPs and patients, as appropriate.

9. How many patients per ODN are expected?

From over 170,000 laboratory reports received by PHE between 1996 to 2017, following successful matching to the NHS Spine patient demographic service and exclusion of those who have died or been treated, approximately 55,000 patient details will be shared with ODNs. If evenly distributed (and they are not) that would equate to approximately 2,600 patients per ODN; in reality the numbers will range from 1,000-5,500 depending on completeness of initial laboratory reporting in their area.

10. How many patients per GP practice are expected?

If these patients are evenly distributed across 7,000 GP practices in England (which undoubtedly they are not), this equates to around 8 patients per practice.

PHE will inform NHSE and ODNs of the number of patients per ODN and highlight any GP practices which have more than 10 patients on the list. Practices with a large number of patients e.g. >40, may need additional administrative support from ODN leads and the CCG.

11. Who do I inform if the patient information is incorrect?

Please inform PHE if you pick up an error in the patient details, either from your local checks of data systems or via the patient’s GP, so we can update our systems. You can email PHE’s national hepatitis team directly and securely with patient confidential information from an nhs.net email address to phe.hepcdiagnoses@nhs.net.

12. Will all correctly identified patients require treatment?

Not all patients identified will be currently infected with hepatitis C and require treatment as laboratory reports to PHE are mostly HCV antibody (ever infected) positive results, not HCV RNA (currently infected) test results which would indicate a need for treatment consideration. Therefore, all patients identified in this re-engagement exercise should have confirmatory HCV RNA testing for viraemia, if not done recently.

13. How does this exercise affect management of newly diagnosed hepatitis C patients?

This retrospective matching exercise does not replace current processes for new laboratory diagnoses of hepatitis C being reported to the requesting clinician and /or direct laboratory reporting to ODNs as part of routine clinical care and locally agreed pathways.

14. How will hepatitis C treatment uptake resulting from this exercise be monitored?

To monitor the impact of this patient re-engagement exercise on hepatitis C treatment uptake, an additional option has been added to the source of referral field in the in the A&G/ NHSE treatment registry called 'HCV re-engagement exercise'. Please use this option for patients who have been referred for treatment as a result of the re-engagement exercise.

Resources available on hepatitis C for GPs and patients

15. Where can I get information for patients on hepatitis C?

Patient resources are available at the following websites:

DH health and social care orderline: https://www.orderline.dh.gov.uk/ecom_dh/public/home.jsf

NHS website: <https://www.nhs.uk/conditions/hepatitis-c/>

The Hepatitis C Trust: www.hepctrust.org.uk

The British Liver Trust: <https://www.britishlivertrust.org.uk/liver-information/liver-conditions/hepatitis-c/>

PHE (for posters, social media banners, videos): <https://publichealthengland-immunisati.app.box.com/s/iptxtlziu57evyejw8zgvhimh0pjwa05>

These resources are all available free of charge and can be used to promote awareness of the risks, the availability of treatment and signpost potential patients to the quiz.

16. What resources on hepatitis C and this exercise are available for GPs?

To support GPs, PHE and NHSE have developed a suite of materials including:

- hepatitis C case finding exercise Q&A for GPs
- hepatitis C FAQ for GPs
- hepatitis C FAQ for patients

These should be circulated to GPs (either enclosed with the GP letter or patient letter, as appropriate).

RCGP has developed a liver disease toolkit which includes resources for healthcare professionals and free e-training modules on hepatitis C (and B)

<http://www.rcgp.org.uk/clinical-and-research/resources/toolkits/liver-disease-toolkit.aspx>

To raise general awareness of hepatitis C (and B) and prompt testing (if at risk) during European hepatitis testing week, World Hepatitis Day and for general promotion, PHE has also developed materials (quiz, video, social media banners, posters, flyers) which are endorsed by the Hepatitis C Trust, British Liver Trust and World Hepatitis Alliance, and are available at: <https://publichealthengland-immunisati.app.box.com/s/iptxtlziu57evyejw8zgvhimh0pjwa05>

The International Network on Hepatitis in Substance Users (INHSU) has online learning modules on assessment and management of hepatitis C in primary care and drug and alcohol settings aimed at clinical staff working with people who inject drugs. Information is available at: <http://www.inhsu.org/education-program/united-kingdom/> and info@inhsu.org.

Caldicott principles and information governance

17. What Caldicott opinion was obtained for release of PHE data to ODNs?

The PHE Caldicott panel approved release of PHE patient confidential data (PCD) for processing by the ODN leads, acknowledging the information governance risks but noting that these could be mitigated. Overall they concluded that these risks were outweighed by the public health benefits in terms of providing treatment to people who may otherwise suffer morbidity and mortality from hepatitis C related liver disease, and by preventing onward transmission of hepatitis C. The National Patient Safety Guardian has also been informed by PHE's Caldicott Guardian.

18. How do I explain to a patient why PHE holds their information and has shared it with another doctor?

Doctors and laboratory directors are mandated by law to report to PHE any new diagnoses of hepatitis C as it is a notifiable disease. PHE collects this information as part of disease surveillance to carry out its legal duty to monitor, prevent and control the spread of infectious diseases, to protect and improve the public's health.

PHE holds this sensitive information confidentially and securely and following Caldicott principles, does not share personal identifiable information with any third party (except with the clinician responsible for the care of the patient, like the patient's GP).

Please see PHE's Personal Information Charter regarding use of personal information and privacy:

<https://www.gov.uk/government/organisations/public-health-england/about/personal-information-charter>

Hepatitis C infection can lead to serious liver disease and cancer if untreated. Past treatments have not been so effective or well tolerated. In recent years new highly effective hepatitis C treatments have become available on the NHS that can cure patients, have fewer side effects and are a shorter oral tablet course. However there is concern that not all those patients who would benefit are aware of their diagnosis or the new treatment options.

PHE has therefore asked for specific Caldicott approval to share a list of patients who have had a previous laboratory diagnosis of hepatitis C with specialist hospital doctors so they may contact the patient for assessment for curative treatment.

Memorandum of Understanding with PHE

19. Why do we need to sign an MOU?

Laboratory reports are provided to PHE under the current PHE permissions for public health surveillance under Section 251 of the NHS Act 2006 and the Health Service (Control of Patient Information) Regulations 2002 (regulation 3 / 'section 251 support'). This allows PHE to process personal confidential data without consent. By giving the data to ODN leads we are *de facto* breaching patient confidentiality. Therefore we need to be assured that all parties are aware that these data are used solely for the purpose for which special Caldicott permission was received, and not, for example, used for research or shared with academic or commercial entities. The MoU also restates the recipient's responsibilities about data security, storage and legitimate sharing of data with those involved in direct patient care.